## REMARKS

Claims 1, 9-13 and 16-22 are in this application and are presented for consideration. By this amendment, Applicant has amended claims 1 and 9-11. Claims 2, 3, 14 and 15 have been canceled.

Applicant has attached an English translation of the International Preliminary Report on Patentability as well as a copy of the corresponding European patent application EP 1 673 030 B1. No Information Disclosure Statement is being submitted for the references cited in the International Preliminary Report on Patentability as these references have been previously cited in Applicant's Information Disclosure Statement of October 11, 2006. Applicant wishes to bring to the Examiner's attention that the features as now claimed in the current application have been allowed in the corresponding European patent application EP 1 673 030 B1.

Applicant wishes to thank the Examiner for speaking with Applicant's representative, Brian M. Duncan, on April 12, 2011. During the conversation with the Examiner, Applicant's representative proposed amending the claims to highlight that the mesh layers are congruent and identical to one another. The Examiner stated that such changes to the claims would overcome the cited prior art reference, but a request for continued examination (RCE) would be necessary in order for the changes to the claims to be considered.

Claim 9 has been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the Office Action states that claim 9 requires the same group of connection points being positioned along the inner and outer edge and that Applicant's application does not support such features.

Applicant has amended claim 9 to clarify at that least one of the connection points is positioned along the inner edge and that at least another of the connection points is positioned along the inner edge. This is clearly shown in Figure 2 of Applicant's disclosure and fully supported by at least paragraphs [0007] and [0015] of Applicant's specification. Accordingly, Applicant respectfully requests that the Examiner remove the rejection as the features claimed are fully supported by Applicant's original disclosure.

Claims 1-3 and 9 have been rejected under 35 U.S.C. 103(a) as being anticipated by Zotti et al. (US 2003/0171823).

Zotti et al. discloses a mesh 1 made of monofilament polypropylene that consists of upper 1' and lower 1" layers joined by welding along almost the entire length of the edges p, with the exception of the zone q corresponding to the fins 5', 5", that are smooth, polished and without ravel. The layers comprise identical coaxial holes 2', 2" from which two radial openings or slits 3', 3" lead off forming an angle  $\Omega$  comprised between 90° and 180°. The zone of the edges q between the slits is not joined but is free generating an upper 5' and lower 5" fin that can be easily bent.

Zotti et al. fails to teach and fails to suggest a first annular mesh layer that is identical to a second annular mesh layer wherein the first annular mesh layer and the second annular mesh layer have a congruent shape as claimed. Zotti et al. merely discloses a flat mesh implant for hernia care having two mesh layers that are superimposed with aligned openings wherein access slits are provided in each of the mesh layer. According to Zotti et al., the access slits of the mesh layers are offset at an angle between 90° and 180°. The shape of the mesh implant

of the mesh layers of Zotti et al. is rotationally asymmetric and has a potato-like contour. According to Zotti et al., the central opening lies eccentrically in relation to center of gravity of the rotationally asymmetric shape. This does not provide any teaching or suggestion for annular mesh layers that are identical to one another as featured in the present invention. The off-set angle  $\Omega$  between both access slits 3', 3" of Zotti et al. is less than 90° as shown in Figure 1. Although Zotti et al. discloses the maximum limit of the off-set angle is 180°, this is disadvantageous since the spermatic duct of the patient has to be introduced from the narrow sides of the hernia mesh to the central openings, which on one side leads to a long threading path due to the eccentric position of the central openings. A further disadvantage of the mesh implant of Zotti et al. is that both mesh layers have to be designed differently due to the asymmetric configuration of the mesh implant. This disadvantageously requires that differently shaped mesh layers be manufactured, stored and processed.

The present invention takes a completely different approach than that of Zotti et al. According to the present invention, the annular mesh layers are of an identical design and have a congruent shape. An implant having identical annular mesh layers are not disclosed in Zotti et al. Zotti et al. discloses that mesh implants have to have a special design in shape to be adapted to the anatomic conditions. The present invention departs from this principal and propagates two absolutely identical circular mesh layers which are connected with each other with off-set access slits. Due to the identical congruent shape of both mesh layers of the present invention, only one single shape of mesh layers has to be cut out, stored and used in production. This advantageously generates a considerable advantage in manufacturing

production and significantly reduces manufacturing costs as a result of the identical design of the annular mesh layers. Due to the identical design of the annular mesh layers of the present invention, a further unexpected advantage is achieved. Knitted polypropylene meshes, like those used for both mesh layers, are anisotropic as to their expansion behavior. The mesh layer is more flexible in one tensioning direction with the net plane compared to an orthogonal tensioning direction within this net plane. With an identical forming of both mesh layers as featured in the present invention, both mesh layers have the same anisotropism in relation to a reference direction defined by the access slits wherein the anisotropism is outweighed by the off-set angle of 180°. The mesh implant of the present invention as a whole is more evenly stretchable in all tensioning directions in the mesh plane and is applicable in a more precise manner. Compared with the present invention, Zotti et al. discloses mesh implants that are rotationally asymmetric and adapted in shape to anatomic conditions. However, Zotti et al. does not provide any teaching or suggestion for the implant having identical mesh layers and the advantages associated with such identical mesh layers as claimed. As such, the prior art as a whole takes a completely different approach and fails to teach or suggest important features of the claimed combination. Accordingly, Applicant respectfully requests that the Examiner favorably consider claims 1, 9, 10 and 11 as now presented and all claims that respectively depend thereon.

Claim 10 has been rejected under 35 U.S.C. 103(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Zotti et al.

As previously discussed above, Zotti et al. does not provide any teaching or suggestion

for a hernia mesh implant that comprises identical annular mesh layers as claimed. Zotti et al. discloses two mesh layers that are not identical, which disadvantageously increases manufacturing costs. As such, Zotti et al. fails to teach or suggest identical mesh layers that have slits that are offset at 180° from each other. Accordingly, Applicant respectfully requests that the Examiner favorably consider claim 10 as now presented.

Claims 11-15 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Zotti et al. in view of Willberg (DE 198 32 634).

Although Willberg teaches a multilayer flat implant for hernia treatment, the references as a whole fail to suggest the combination of features claimed. Specifically, Zotti et al. and Willberg provide no suggestion or teaching for a first mesh layer that is identical to a second mesh layer wherein the slits of the first mesh layer and the second mesh layer are offset at 180° from each other. As such, the references together do not teach or suggest the combination of features claimed. One of ordinary skill in the art is presented with various concepts, but these concepts do not provide any direction as to combining the features claimed. All claims define over the prior art as a whole.

Favorable consideration on the merits is requested.

Respectfully submitted For Applicant,

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- and -

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Attached: English Translation of International Preliminary Report on Patentability

Copy of EP 1 673 030 B1

Petition for Two Month Extension of Time

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